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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,812

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Anders Reden

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26 PINECREST PLAZA, SUITE 2
SOUTHERN PINES, NC 28387-4301

EXAMINER

SHOME, ARUNDIPTA

ART UNIT

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,812	Applicant(s) REDEN ET AL.	
	Examiner ARUNDIPTA SHOME	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-19-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1- 10 are pending.

Drawings

1. Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding Claim 1, the specification does not contain adequate written description for the claimed "openings to receive a tube" because it appears that only one opening receives a tube.

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Regarding Claim 7, the specification does not contain adequate written description for the step of “evaporated medication flowing on an outside of the tube and over the tube before entering the opening.”

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, there is a lack of antecedent basis for “the housing” on line 11, and “the opening” on line 19. Additionally, it is recited that air is “moisturized by the filter” on lines 16-17, but it is unclear how a filter can moisturize air.

Regarding Claim 2, “the tube” is recited on line 2, but there are two tubes recited in claim 1, clarification of which tube is being referred to is needed.

Regarding Claim 3, “the opening” is recited on line 3 but it is unclear which previously recited opening this is in reference to, because the numbers in parentheses cannot be used to distinguish the different elements of the claim.

Regarding Claim 4, “an opening” is recited on line 3 and “the opening” is recited on line 4, the claim is indefinite for the same reason noted with respect to claim 3.

Regarding Claim 5, “openings” are recited on line 3, and is indefinite for the same reason noted with respect to claim 3.

Regarding Claim 6, there is a lack of antecedent basis for “the valve” on line 4.

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Regarding Claim 7, “the opening” is recited on line 4, and it is unclear which previously recited opening this refers to, and there is a lack of antecedent basis for this recitation.

Regarding Claim 8, there is a lack of antecedent basis for “the airflow” on line 3. Additionally, “an opening” is recited on line 3 as well, and it is unclear which opening this refers to.

Regarding Claim 10, “an opening” is recited on line 3.

The Examiner recommends reciting a first opening, second opening, etc. to differentiate the various openings in the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4 and 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kidwell (US Patent 6,328,030) in view of Johnson (US Patent 7,204,245), further in view of Altadonna (US Patent 5,505,768).

Regarding Claim 1, Kidwell discloses a nebulizer with an upper housing 15 engaged with a lower housing 52. The upper housing has openings to receive a tube (Fig. 1).

The nebulizer is connected downstream of incoming air of an inhale tube (see connection to the respirator/ventilator, Fig. 1) and upstream of a connector (port 16).

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Pressurized air is added in a tube 61 (Fig. 1) connected to the bottom of the housing. The air is exposed to a liquid medication in the housing (col. 1, lines 22-25), and aerosolizes the liquid medication into aerosolized medication (col. 8, line 50).

The aerosolized medication then mixes with inhaling air provided by a ventilator (Fig. 1). The aerosol medication then flows into an opening of the tube connected to the patient (Fig. 1).

Kidwell does not disclose that the upper and lower housings have semi-spherical shapes. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of the upper and lower housings to be semi-spherical because it has been held that a simple change in shape is generally obvious to one of ordinary skill in the art. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Kidwell does not disclose an upward opening on the tube. Johnson teaches a nebulizer with a tube connecting to the patient with an opening (valve 38, Fig. 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient connecting tube of Kidwell to have an opening as taught by Johnson because the opening is part of a valve that allows inhalation from the ventilator and expels expiratory flow (see col. 4, lines 55-60 of Johnson). Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the opening of Johnson to be an upward opening so that warm exhaled air is directed away from the opening and rises away from the tube.

Kidwell does not disclose a filter upstream of the nebulizer that moisturizes air. Altadonna teaches a heat and moisture exchanger with a filter 18 (col. 4, lines 45-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

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modify the nebulizer system of Kidwell to include a heat exchanger as taught by Altadonna located upstream of the nebulizer because it is well known in the art that heat and moisture exchangers are useful for moisturizing air that is delivered to a ventilated patient.

Regarding Claim 2, the modified Kidwell system has a tube that connects to the patient and includes the valve 38 of Johnson. The valve 38 of Johnson appears to have a bottom inner wall with a steep section that expels air out of the tube, and a gentle section that conducts the inhalation stream to the patient (see Fig. 4 of Johnson).

Regarding Claim 3, Figure 4 of Johnson shows the steep section causing a turbulent air flow that exits through the opening in the tube.

Regarding Claim 4, Johnson shows in Figure 4 that the gentle section causes an airflow that exits through an opening of the tube connected to a patient, without escaping through the exhalation opening (see col. 4, lines 55-60 of Johnson).

Regarding Claim 9, the nebulizer of Kidwell could be rotated by a small angle degree while still permitting the pressurized air to encounter the liquid medication.

Regarding Claim 10, the upper housing has an opening 31 for receiving the liquid medication from the lower housing.

8. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kidwell in view of Johnson, further in view of Altadonna as applied to claim 1 above, and further in view of Grychowski (US PGPub 2003/0015193).

Regarding Claim 5, Kidwell does not disclose a valve with openings on the lower housing to permit pressurized air into contact with the liquid medication. Grychowski teaches a nebulizer with a valve having openings 44 (Fig. 2) on a lower portion of the nebulizer housing,

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and these openings permit pressurized air into contact with the liquid medication (para. 0034, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the lower housing 50 of Kidwell with the entire lower portion of the nebulizer 22 as taught by Grychowski because both nebulizers were known in the art and would perform equally well, and Kidwell states that any particular nebulizer can be used with the invention (col. 5, line 32).

Regarding Claim 6, the modified Kidwell device as noted with respect to claim 5 includes a conical wall 40 to create a channel between the wall and the valve 24 (see Fig. 2 of Grychowski, and para. 0034, lines 1-10).

Regarding Claim 7, the modified Kidwell device as noted with respect to claim 5 includes evaporated medication flowing over the tube 32 of Grychowski (para. 0034, lines 1-10) and over the tube before entering the upward opening noted for claim 1.

Regarding Claim 8, the medication mixes with the airflow prior to exiting through an opening of the tube.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wallace (US Patent 5,036,840) discloses a nebulizer for a ventilator system.

Svoboda (US Patent 4,746,067) discloses an atomizer with a conical wall.

Enfield (US Patent 3,874,379) discloses a nebulizer system for a breathing circuit.

Lindsey (US Patent 4,263,907) discloses a similar nebulizer system.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 9:00am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Arun Shome/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771